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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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CONEY ISLAND PREP, et al.,

Plaintiffs,

- against -

UNITED STATES DEPARTMENT OF HEALTH  
AND HUMAN SERVICES, et al.,

Defendants.  
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**VICTOR MARRERO, United States District Judge.**

Plaintiffs Coney Island Prep ("CIP"), Leslie-Bernard Joseph ("Joseph"), Housing Works, Inc. ("Housing Works"), Charles King ("King"), New York City Councilmember Mark Levine ("Levine"), and Alexandra Greenberg ("Greenberg") (collectively, "Plaintiffs") brought this action against the United States Department of Health and Human Services ("HHS"), Secretary of HHS Alex Azar ("Azar" or the "Secretary"), Assistant Secretary of HHS Robert Kadlec ("Kadlec"), the Centers for Disease Control and Prevention ("CDC"), and Director of the CDC Robert R. Redfield ("Redfield") (collectively, "Defendants" or the "Government"). Plaintiffs allege that Defendants failed to abide by certain of their statutory obligations to provide reports or allow public participation opportunities related to public health issues such as the pandemic response. (See

Complaint, Dkt. No. 1 ¶¶ 6-8.) Plaintiffs also allege that Defendants acted in an arbitrary and capricious manner in violation of the Administrative Procedure Act ("APA") by switching the database used for reporting daily COVID-19 hospitalization statistics. (See id. ¶¶ 140-48.)

Plaintiffs moved for a Preliminary Injunction requiring Defendants to provide the outstanding reports and participation opportunities and return to the previously used database for COVID-19 hospitalization statistics. (See Motion, Dkt No. 6; Plaintiffs' Memorandum of Law ("Pls. Mem."), Dkt. No. 7) Defendants opposed the motion. (See Opposition, Dkt. No. 33) The Court subsequently held a telephone conference on December 2, 2020, during which it heard the parties' arguments as to whether Plaintiffs had demonstrated irreparable harm and a likelihood of success on the merits, among other issues such as standing. (See Docket Minute Entry Dated December 2, 2020).

For the reasons that follow, the Court DENIES Plaintiffs' motion for a preliminary injunction.

## **I. BACKGROUND**<sup>1</sup>

### **A. PLAINTIFFS' ALLEGATIONS**

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<sup>1</sup> The factual background herein derives from the Complaint, as well as from the exhibits filed in connection with Plaintiffs' Memorandum of Law and Defendants' Opposition. Except when specifically quoted or referenced, no further citation to these sources will be made.

Plaintiff CIP is a public charter school in Brooklyn, New York that serves a diverse community of students and families from the Coney Island Area. CIP's Chief Executive Officer ("CEO") is plaintiff Joseph. Plaintiff Housing Works is a New York City nonprofit that addresses homelessness, HIV/AIDS, and "other chronic health conditions." (Complaint ¶ 18.) Housing Works operates health clinics, supportive housing centers, career training programs, legal services, and profitable thrift stores, a bookshop, and a café. Housing Works has partnered with New York City agencies to offer free COVID-19 testing and to operate housing centers to isolate and quarantine infected or exposed persons. Plaintiff King is the CEO and founder of Housing Works. Plaintiff Levine is a New York City Councilmember representing the 7th District in Northern Manhattan and serving as the Chair of the Council Committee on Health. Plaintiff Greenberg is a medical student at SUNY Downstate College of Medicine and "a public health researcher and advocate." (Id. ¶ 21.)

Plaintiffs bring two claims under the APA. First, Plaintiffs argue that Defendants have failed to take legally required action, in violation of Section 706(1) of the APA, 5 U.S.C. § 706(1). Second, Plaintiffs argue that

Defendants acted arbitrarily and capriciously in switching the databases holding COVID-19 hospitalization data, in violation of Section 706(2) of the APA, id. § 706(2). Based on the factual allegations underpinning these claims, Plaintiffs also seek relief under the All Writs Act, 28 U.S.C. § 1651(a), and the Mandamus Act, id. § 1361.

More specifically with respect to their Section 706(1) claim, Plaintiffs allege that Defendants failed to timely comply with certain statutory obligations that fall under three umbrella categories: (1) duties pertaining to biosurveillance efforts; (2) reporting obligations; and (3) obligations to allow public participation in formulating policy responses relating to various public health issues.

With respect to Defendants' biosurveillance duties, Plaintiffs allege that Defendants have failed to perform the following required tasks: (1) promulgate technical and reporting standards to coordinate the gathering of public health data pursuant to 42 U.S.C. § 247d-4(b)(2)-(3) with notice and comment; (2) publish these technical and reporting standards; (3) complete a Biological Threat Detection Report as required by the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (the "Pandemic Preparedness Act"), Pub. L. No. 116-22 §

205, 133 Stat. 905, 924-25; and (4) convene a public meeting for purposes of discussing and providing input on the potential goals, functions, and uses of a biosurveillance network pursuant to 42 U.S.C. § 247d-4(c)(5)(B). (Complaint ¶ 121.)

With respect to reporting obligations, Plaintiffs allege that Defendants have failed to issue reports (1) on the medical countermeasures budget, as required by 42 U.S.C. § 300hh-10(b)(7); (2) on the medical countermeasures plan, as required by 42 U.S.C. § 300hh-10(d); (3) from state and local agencies receiving federal funding for public health security and surge capacity, as required by 42 U.S.C. §§ 247d-3a(i)-(j), 247d-3b(i); (4) regarding biological agents, toxins, and related medical countermeasures, as required by 42 U.S.C. § 262a(k); (5) on a Threat-Based Review of the Strategic National Stockpile ("SNS") of Countermeasures for use in the event of a public health emergency, as required by 42 U.S.C. §§ 247d-6b(c)(2)(C), (3); (6) on national health resources and statistics, as required by 42 U.S.C. § 242m(a)(1)-(2); (7) of a national disease prevention data profile, as required by 42 U.S.C. § 242p; (8) on disparities by race and ethnicity, as required by 42 U.S.C. § 299a-1(a)(6); (9)

from the Office of Minority Health, as required by 42 U.S.C. § 300u-6(f); (10) on international cooperation in the research and development of vaccines and other qualified pandemic or epidemic countermeasures, as required by the Pandemic Preparedness Act, 133 Stat. at 959; and (11) on maintaining an adequate national blood supply for emergency response, as required by the Pandemic Preparedness Act, 133 Stat. at 929.

With respect to public participation opportunities, Plaintiffs allege that Defendants have failed to (1) solicit input from experts to aid executive medical countermeasures planning pursuant to 42 U.S.C. § 300hh-10(d)(2)(H), and (2) to convene a meeting on genomic engineering for health security and public health emergency countermeasures development pursuant to the Pandemic Preparedness Act, 133 Stat. at 958-59.

As to Plaintiffs' Section 706(2) claim, Plaintiffs allege that Defendants have shifted the reporting of daily COVID-19 hospitalization statistics from the CDC's publicly available National Healthcare Safety Network ("NHSN") "to a privately managed HHS Protect database, denying public access to such information and adding further difficulty to state and local officials, health researchers, and the

wider public who rely on transparent data and disclosures.”

(Complaint ¶ 140.)

Plaintiffs claim that they have been injured by Defendants’ conduct. In the Complaint, Plaintiffs state that they

have been denied vital information with respect to the Covid-19 pandemic -- its spread and prevalence in the community, the comprehensiveness of the data collected and made available, and the nation’s capacity and efforts to respond effectively -- that is critical to their ability to conduct themselves safely and to protect their members and communities from adverse outcomes during this public health crisis. Plaintiffs have also been injured in that they have been denied procedural opportunities to participate in and give notice and comment on vital aspects of the government’s pandemic preparations and response capacity. Absent such opportunities, Plaintiffs -- all of whom play vital roles in the health and safety of their communities -- have lost the opportunity to contribute their needs and knowledge to the regulatory process. Such injuries have also forced Plaintiffs to divert resources that they would have dedicated otherwise.

(Complaint ¶¶ 131-33). Plaintiffs’ Memorandum of Law reiterates that “[t]he lack of information -- about, among other things, the development of ‘biosurveillance’ capabilities to track the pandemic in ‘near real-time,’ existing public health emergency capacities, Americans’ underlying health and health resources, and the need or ability to protect those most vulnerable to adverse

outcomes -- cripples Plaintiffs' capacity to conduct themselves and their organizations safely and effectively during the pandemic." (Pls. Mem. at 11.)

As to Defendants' alleged failure to convene the required meetings and notice-and-comment process, Plaintiffs argue that they are injured because "Plaintiffs are entitled to participate in the mandated public health emergency planning and would bring valuable insight to the discussions." (Id. at 14.) Plaintiffs also argue that Defendants' disregard for these opportunities has delayed biosurveillance and public health measures, which ultimately harms Plaintiffs, and "places Plaintiffs at risk of being subject to or harmed by uninformed, let alone unlawful, government action." (Id. at 14-15.)

Finally, Plaintiffs claim that Defendants' conduct causes CIP and Housing Works harm "by causing them to divert resources from prior organizational goals to other efforts, such as to protect and inform their communities, provide care for sick or at-risk community members, or devise alternative procedures to confront the threat of Covid-19." (Id. at 16.)

B. DEFENDANTS' ARGUMENTS

Defendants dispute Plaintiffs' claims that they have

failed to meet their relevant statutory duties. As an initial point, Defendants state that the creation and implementation of a biosurveillance program is not statutorily due until September 2023. See 42 U.S.C. § 247d-4(g).

Defendants further represent that they either have completed or are near completion of many of the requirements. For instance, Defendants have partially met the requirement to adopt technical and reporting standards, a process which Defendants contend does not require notice and comment. In addition, Defendants have solicited public comments on the report relating to the national blood supply and are in the process of incorporating that feedback; they estimate completing the report by January 2021. The relevant agency official in charge of submitting an annual report on racial disparities in healthcare is expected to submit this year's report by the end of this year. Defendants further represent that HHS has prepared the report on international cooperation and expects to finalize and publish the report by the end of this year. Similarly, HHS's report on biological agents, toxins, and related countermeasures has been prepared, and HHS plans to submit the report by the end of this year.

As to participation opportunities, Defendants convened an informal meeting in July 2020 regarding biosurveillance activities and led a meeting in October 2019 on bioeconomy leadership in connection with the requirement to hold meetings on genomic engineering technologies.

Defendants acknowledge that some publications are delayed. For example, the annual Threat-Based Review of the SNS for 2020 is still awaiting reasonable deliberation and review, and it will be submitted to Congress by the end of the first quarter in 2021. Similarly, annual reports on national health resources and statistics are in the final stages of being finalized and are expected to be published shortly soon. The 2017 Report from the Office of Minority Health is under final review, the 2019 Report is under development, and development of the 2021 Report will begin by the end of the year.

Defendants also admit that they have so far failed to draft a Biological Threat Detection Report, but plan to do so by January 2021. Defendants also have failed to submit this year's budget plan, although they represent that past reports are available.

As to Plaintiffs' alleged harm, Defendants argue that Plaintiffs have not sufficiently alleged any injury.

Defendants explain that the relevant statutory provisions require only that Defendants provide information to Congress, not to Plaintiffs or the general public. Though Defendants acknowledge that some provisions do require Defendants make information available to the general public, Defendants state that "Plaintiffs have entirely failed to explain how any delay in the provision of each of these reports to the public led to a concrete, particularized or imminent injury," especially in light of the fact that none of the outstanding reports are directly related to COVID-19. (Opposition at 24-25.) Defendants also contend that Plaintiffs have failed to articulate how any specific report would assist Plaintiffs in responding to the pandemic.

## **II. LEGAL STANDARD**

To obtain a preliminary injunction, a plaintiff must show: "(1) irreparable harm; (2) either a likelihood of success on the merits or both serious questions on the merits and a balance of hardships decidedly favoring the moving party; and (3) that [the requested relief] is in the public interest." N. Am. Soccer League, LLC v. U.S. Soccer Fed'n, 883 F.3d 32, 37 (2d Cir. 2018). In order to receive a mandatory injunction compelling action, a plaintiff must

meet a heightened standard and make "a strong showing of irreparable harm" as well as a "clear or substantial likelihood of success on the merits." Yang v. Kosinski, 960 F.3d 119, 127-28 (2d Cir. 2020) (citation omitted).

The showing of irreparable harm "is the single most important requisite." LSSi Data Corp. v. Time Warner Cable, Inc., 892 F. Supp. 2d 489, 501 (S.D.N.Y. 2012) (internal quotation marks and citation omitted). To demonstrate irreparable harm, the movant must show "an injury that is neither remote nor speculative, but actual and imminent." Rodriguez v. DeBuono, 175 F.3d 227, 234 (2d Cir. 1999) (internal quotation marks and citation omitted). The movant must further show that the injury "cannot be remedied by an award of monetary damages." Id.

"When considering a motion for a preliminary injunction, unlike a motion to dismiss, the Court need not accept as true the well-pleaded allegations in Plaintiff['s] complaint." Victorio v. Sammy's Fishbox Realty Co., No. 14 Civ. 8678, 2014 WL 7180220, at \*4 (S.D.N.Y. Dec. 12, 2014) (citing Incantalupo v. Lawrence Union Free Sch. Dist. No. 15, 652 F. Supp. 2d 314, 317 n.1 (E.D.N.Y. 2009)).

### **III. DISCUSSION**

The Court is not persuaded that Plaintiffs have met their burden of making a strong showing of irreparable harm. Plaintiffs allege three types of harm: (1) harm stemming from deprivation of information; (2) harm stemming from procedural violations; and (3) organizational harm to CIP and Housing Works. For the reasons set forth below, the Court concludes that Plaintiffs have failed to sufficiently allege irreparable harm. Accordingly, although Defendants raise a number of arguments as to why Plaintiffs are not entitled to a preliminary injunction -- including because they lack standing, have not shown a likelihood of success on the merits, and have not shown that the public interest favors the relief requested -- the Court need not, and does not, reach these arguments.

A. INFORMATIONAL INJURY

Nondisclosure of information can support a finding of irreparable harm when a plaintiff shows that "absent preliminary injunctive relief," the lack of information "substantially impair[s] [the plaintiff] in a manner that is both 'certain and great.'" Lawyers' Comm. for Civil Rights Under Law v. Presidential Advisory Comm'n, 265 F. Supp. 3d 54, 70 (D.D.C. 2017); see also Seife v. U.S. Dep't of Health & Human Servs., 440 F. Supp. 3d 254, 272

(S.D.N.Y. 2020) (“[A] plaintiff suffers a sufficiently concrete and particularized injury to confer Article III standing when [1] she is denied access to information that, in the plaintiff’s view, must be disclosed pursuant to a statute and [2] there is no reason to doubt that the information would help the plaintiff within the meaning of the statute.”) (internal quotation marks and citation omitted).

Even assuming that Plaintiffs are entitled to the information at issue,<sup>2</sup> Plaintiffs have not sufficiently alleged an irreparable informational injury. Plaintiffs cannot show that the lack of this information causes them a “certain and great impairment,” and Plaintiffs have also failed to show that this information would undoubtedly be helpful to Plaintiffs. This is especially true in light of the fact that the vast majority of information at issue does not pertain directly to the COVID-19 pandemic.<sup>3</sup>

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<sup>2</sup> It is not certain that Plaintiffs are entitled to much of the information at issue, as many of the statutory provisions relied on only require the Secretary to provide reports or other information to Congress. See, e.g., 42 U.S.C. § 242m(a)(1)-(2); id. § 242p; Section 205(c), 133 Stat. at 924-25. However, the Court does not need reach this question.

<sup>3</sup> Plaintiffs’ counsel during oral argument seemed to acknowledge that the reports are not directly relevant to COVID-19. Plaintiffs’ counsel primarily argued that the reports are relevant to general pandemic preparedness, so “[i]nformation on the government’s preparation and capacity to respond to all public health emergencies, including the present pandemic, would aid plaintiffs’ advocacy efforts and avoid

# 1. Withheld Reports and Data

Plaintiffs' allegations primarily consist of broad assertions as to the usefulness of information generally, without specifying what information in the reports at issue would be useful or how that information would help them. For instance, the Complaint states that Plaintiffs have been denied "vital information with respect to the Covid-19 pandemic" such as "its spread and prevalence in the community, the comprehensiveness of the data collected and made available, and the nation's capacity and efforts to respond effectively" -- information "that is critical to their ability to conduct themselves safely and to protect their members and communities from adverse outcomes during this public health crisis." (Complaint ¶ 131.) But while Plaintiffs allege that the information is "critical," Plaintiffs have failed to explain *why* the information is critical, how it would actually benefit them, or if the information is not otherwise publicly available.<sup>4</sup>

Similarly, Plaintiffs' Memorandum of Law states that

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duplication at the community level." (Oral Argument Tr., Dkt. No. 45, at 8:10-13.) This argument is discussed below.

<sup>4</sup> The Court takes judicial notice of the fact that there is a significant amount of information on COVID-19, including information on its spread and prevalence, already available. See, e.g., COVID-19: Data, NYC Health, <https://www1.nyc.gov/site/doh/covid/covid-19-data.page> (last visited Dec. 11, 2020). Plaintiffs have not adequately

the lack of information “cripples” their efforts to conduct themselves safely during the pandemic without a detailed explanation as to how. Instead, Plaintiffs make conclusory statements. For example, Plaintiffs state that the denial of information “inhibits [CIP] from assessing Covid-19’s threat to its community members, implementing policies to mitigate Covid-19 transmission, providing in-person and remote programs to fulfill its educational mission, evaluating programs and interventions by other schools and in other jurisdictions, and advocating on behalf of itself and its community for improved public health interventions and educational policies.” (Pls. Mem. at 11.)

But Plaintiffs have failed to demonstrate how the information they seek would in fact help CIP in achieving these goals. As a result, it would require speculation on the part of the Court to conclude that the information would help Plaintiffs, and a further jump to conclude that they would suffer a certain and great harm in its absence. Had Plaintiffs instead provided more specific details, such as by stating that CIP institutes remote learning based on a certain set of data like available hospital capacity or COVID-19 prevalence, and adduced enough evidence to support

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described what data, beyond what is publicly available, is needed or

a finding that such data is contained in the withheld reports, Plaintiffs may have met their burden of making a strong showing of irreparable harm. But the record is devoid of allegations such as these.

Likewise, Plaintiffs state that Housing Works "depends on the information the Administration has denied to determine protocols for day-to-day operations to 'direct isolation, treatment, and preventative care' -- particularly with respect to the communities of color it serves -- to 'tailor services to address inequities,' and to develop 'concrete plans to improve the health of communities of color.'" (Id.) But Plaintiffs do not explain what specific withheld information is needed or how that information would in fact assist Housing Works in the manner described.

Furthermore, Plaintiffs assert that the lack of information to make public health decisions has been a challenge for policymakers like Levine and that "the lack of transparent national data restricts Levine from implementing better policies to prevent transmission from out-of-state travelers as well as evaluate municipal interventions in other jurisdictions." (Id.) Plaintiffs

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why.

also assert that the lack of data about COVID-19 “has hindered Plaintiff Greenberg’s efforts to advocate for health equity and better policy in response to Covid-19.” (Id. at 12.) But these allegations are even less detailed than those provided for CIP and Housing Works. At best, these allegations establish that Levine and Greenberg lack information generally. They do not establish that Levine and Greenberg would be assisted by the data allegedly withheld. This deficiency is particularly glaring in light of the fact that none of the allegedly withheld reports directly pertains to the COVID-19 pandemic.

Plaintiffs’ declarations do a somewhat better job of detailing the need for information, but they too are insufficient for various reasons. For example, Plaintiffs allege the need for information that is not part of the withheld reports. For instance, Joseph, King, and Levine all discuss a need for a biosurveillance network and near real-time data on COVID-19 in order to tailor safety protocols or policy. (See Joseph Decl., Dkt. No. 9, ¶ 28; Levine Decl., Dkt. No. 11, ¶ 13.) But a biosurveillance network that will track such data is not statutorily required until 2023. None of the declarations address the usefulness of the other biosurveillance-related information

for which the statutory deadlines have passed, such as the Biological Threat Detection Report and the technical and reporting standards. According to the Pandemic Preparedness Act, that information could inform Plaintiffs about, among other things, "technological, operational, and programmatic successes and failures of domestic detection programs supported by Federal departments and agencies for intentionally introduced or accidentally released biological threat agents and naturally occurring infectious diseases," 133 Stat. at 924 (detailing the Biological Threat Detection Report), but Plaintiffs have not established how their awareness of that information would assist them in tailoring their COVID-19 response.

Similarly, Levine and Joseph both discussed the usefulness of seeing how other schools and day care facilities are handling COVID-19. (Levine Decl. ¶ 24; Joseph Decl. ¶ 37.) But there is no evidence that any of the relevant reports would contain this information relating to COVID-19 or schools, and neither Levine nor Joseph identify what other reports or withheld data at issue would be helpful for this purpose.

Moreover, Levine states that data on racial health disparities and recommendations on closing those gaps are

necessary to craft responsive policy. (Levine Decl. ¶ 21; see also Joseph Decl. ¶ 39.) But it is not at all clear that the statutorily required reports from the Office of Minority Health, which must be submitted to Congress biannually, would contain that information; the reports are meant to describe the subagency's activities and "evaluat[e] the extent to which such activities have been effective in improving the health of racial and ethnic minority groups." 42 U.S.C. § 300u-6(f)(1). And it is not apparent from Levine's declaration how the information on the agency's activities and the effectiveness of those activities would assist Levine in setting local policy. And while the Secretary must "submit to the Congress a report regarding prevailing disparities in health care delivery as it relates to racial factors and socioeconomic factors in priority populations" under 42 U.S.C. § 299a-1(a)(6), Plaintiffs Levine and Joseph have made no allegations regarding how information on racial disparities in health care "delivery" would help them. Regardless, the Government's evidence suggests that it is on track to issue this report on disparities in health care delivery by the end of the year. (Perry Decl. ¶ 4.)

Finally, the declarations also iterate a need for

information on federal COVID-19 or biothreat countermeasures. King states that "understanding federal planning and supplies of medical countermeasures can help us anticipate and prepare for shortfalls in specific areas, or position us to advocate for their targeted deployment where they can have the greatest impact." (King Decl., Dkt. No. 10, ¶ 54.) Levine also stated that "information with respect to the federal preparations of medical countermeasures is critical to preventing New York City from needlessly duplicating supplies or efforts already accomplished at the federal level." (Levine Decl. ¶ 22.) But Defendants' evidence suggests that this year's Countermeasures SIP does not focus on COVID-19 and instead is "a strategy for future efforts" that "broadly addresses research and development, acquisition and stockpiling, expanding manufacturing, and planning for distribution and dispensing for all of these countermeasures." (Bratcher-Bowman Decl. ¶ 7.) Accordingly, it does not seem that the type of information useful to Plaintiffs is contained in the Countermeasures SIP, and it is not clear how the information that is actually contained in that report would benefit Plaintiffs.

Similarly, although Plaintiffs suggest a need for

information on federal supplies, Defendants' evidence suggests that the "Threat-Based Review of the SNS has no bearing on the Government's COVID-19 response, as the review is a routine, five-year projection of budgetary priorities for expenditures to maintain current or acquire future medical countermeasure[s] for all threats." (Id. ¶ 13.) It is not apparent from this description that the Threat-Based Review of the SNS would help Plaintiffs in assessing federal supplies level, and Plaintiffs have not adequately demonstrated that the withheld reports otherwise contain the information they would need for that purpose.

A further issue with Plaintiffs' declarations is that they, like Plaintiffs' Complaint and Memorandum of Law, make conclusory representations. Joseph, for example, attested that "[t]he information and reports that the government failed to provide would help CIP and me understand the wider public health risks we face, interpret and evaluate programs of our partners and vendors, understand the successes and failures in other jurisdictions, plan for adverse eventualities, and manage decisions with respect to staffing, training and procurement protocols." (Id. ¶ 34.) He noted that CIP pays close attention to the latest public health information.

(Id. ¶ 35.) But Joseph does not provide any factual basis by which the Court can determine that the information contained in the reports would help him and CIP. Joseph does not identify specific information in specific reports, nor does he explain with any particularity how the information at issue would help. While the Court acknowledges that data often informs decisionmaking, Plaintiffs have not established precisely what data they need or how they would use that data to achieve their undoubtedly commendable goals.

In addition, King's declaration notes that information on topics such as "disease prevalence and co-morbidities" is "relevant" to their day-to-day healthcare programs and COVID-19 care. (King Decl. ¶ 53). But relevant information is not necessarily helpful information, and nothing in King's declaration establishes the helpfulness of the information. In other words, even assuming this information is contained in the records being sought, King fails to explain how this information would be used to benefit Housing Works's COVID-19 response in a real or concrete way.

The declarations of Plaintiffs' experts fail for the same reasons that the declarations of Plaintiffs are

deficient. For example, although Plaintiffs point to the declaration of Dr. Irwin Redlener ("Redlener") ("Plaintiffs' Reply," Dkt. No. 41, at 5 nn. 6-7), Redlener's declaration outlines the need for information not contained in the relevant reports. Redlener states the need for "real-time information," "reports on health disparities along race and ethnicity," and information related to COVID-19 transmission. (Redlener Decl., Dkt. No. 13, ¶¶ 12, 15, 16.) But as discussed above, there is no showing that any of this information is contained in the reports at issue. In addition, Redlener states that "the reports and information that the government has failed to provide are essential to the ongoing operations of my academic and public health practices." (Id. ¶ 15.) But Redlener fails to explain what information is essential and why it is essential. This conclusory allegation is insufficient to show that Plaintiffs would be impaired in a great and certain way absent the information they seek.

In short, Plaintiffs have failed to satisfy their burden of making a strong showing of irreparable harm based on the informational injuries they allege. Plaintiffs either make conclusory statements about the usefulness of information or discuss the need for information not

seemingly encompassed by the relevant reports or data. Plaintiffs have thus not demonstrated how the information contained in the withheld reports would in fact benefit their response to the COVID-19 pandemic. As such, any conclusion that the deprivation of information irreparably harms them "in a manner that is both 'certain and great,'" Lawyers' Comm. for Civil Rights Under Law, 265 F. Supp. 3d at 70 (D.D.C. 2017), would be speculative.

## 2. July 13 Guidance

Plaintiffs' claims of informational injury stemming from HHS's shift from reporting data to NHSN to HHS Protect, which Plaintiffs contend is less transparent, also do not support a finding of irreparable harm. Although Plaintiffs allege that "[p]ublic health officials, researchers, health systems and hospitals all relied on the NHSN data to make informed decisions about allocation of resources and other aspects of their response to the pandemic," (Complaint ¶ 64), Plaintiffs are not public health officials, researchers, health systems, or hospitals, and Plaintiffs do not themselves allege accessing or using the data in the NHSN or HHS Protect databases. Accordingly, the Court fails to see how the deprivation of this information, or the database switch

more broadly, has harmed Plaintiffs in a concrete way.

B. PROCEDURAL INJURY

"With regard to procedural violations . . . a plaintiff must independently establish irreparable harm in order to support preliminary relief." Karen L. ex rel. Jane L. v. Health Net of N.E., 267 F. Supp. 2d 184, 191 (D. Conn. 2003) (citing Jayaraj v. Scappini, 66 F.3d 36, 40 (2d Cir. 1995)). "For the purposes of a preliminary injunction, courts will not base a finding of 'irreparable injury' on a procedural violation standing alone." Am. Ass'n for Homecare v. Leavitt, No. 08 Civ. 0992, 2008 WL 2580217, at \*5 (D.D.C. June 30, 2008). However, courts have said that "the harm suffered by those who would otherwise participate in agency rulemaking under the APA is to be considered irreparable when the agency fails to afford them their rights to such participation." Nat'l Treasury Empls. Union v. Newman, 768 F. Supp. 8, 10 (D.D.C. 1991) (internal quotation marks and citation omitted).

Plaintiffs fail to establish irreparable harm stemming from the alleged procedural violations for two reasons. First, Plaintiffs cannot demonstrate that they were in fact denied any of their participation rights. Second, Plaintiffs fail to demonstrate how the procedural

violations cause them harm.

Although Plaintiffs allege that they “are entitled to participate in the mandated public health emergency planning,” (Pls. Mem. at 14), the relevant statutory provisions do not support this assertion. For instance, while Plaintiffs claim that Defendants failed to provide for formal notice and comment with respect to the promulgation of technical and reporting standards, 42 U.S.C. § 247d-4(b)(2) does not require that these standards be promulgated through notice-and-comment rulemaking. Plaintiffs do not cite to any other case or legal authority to support the claim that notice-and-comment rulemaking was required.

In addition, though Plaintiffs argue that Defendants denied them participation rights by failing to convene a public meeting for purposes of discussing potential goals, functions, and uses of the biosurveillance network, the relevant statutory provision specifies the participants of such a meeting. The statute defines the participants as “representatives of relevant Federal agencies . . .; State, local, Tribal, and territorial public health officials; stakeholders with expertise in biosurveillance and situational awareness; stakeholders with expertise in

capabilities relevant to biosurveillance and situation awareness . . .; and other representatives as the Secretary determines appropriate.” Id. § 247d-4(c)(5)(B)(ii). But Plaintiffs do not fit into any of these categories. Even Levine, though a public official, is not a “public health official.” Although that term is not defined by the statute, it is clear from the surrounding terms that this term refers to an individual employed by a public health department who has some level of subject-matter expertise. See, e.g., Pfizer Inc. v. United States, 939 F.3d 173, 178 (2d Cir. 2019) (explaining that under the canon of construction *noscitur a sociis*, “a word is known by the company it keeps” (internal quotation marks omitted)).

The remaining opportunities -- the input of experts and stakeholders in public health emergency countermeasures planning as part of the Countermeasure SIP process and a meeting on genomic engineering -- similarly would not include Plaintiffs. Although the statute requires “input from Federal, State, local, and tribal stakeholders” to be incorporated into the development of the Countermeasure SIP, 42 U.S.C. § 300hh-10(d)(2)(H), Plaintiffs have not demonstrated that they would be considered “stakeholders.” Moreover, Defendants provide evidence to suggest that this

requirement has been satisfied. (Bratcher-Bowman Decl. ¶ 15.) The requirement in the Pandemic Preparedness Act for meetings on genomic engineering technologies also refers to “representatives from academic, private, and nonprofit entities with expertise in genomic engineering technologies, biopharmaceuticals, medicine, or biodefense, and other relevant stakeholders.” 133 Stat. at 958. Defendants assert that “relevant stakeholders” constitute “people, companies, academicians and government personnel that are actively involved in advanced biotechnology work,” (Bratcher-Bowman Decl. ¶ 16), a conclusion supported again by the canon of *noscitur a sociis*.

Nor do Plaintiffs provide any other persuasive reason that the alleged procedural violations cause them irreparable harm. Plaintiffs argue that the failure to take the above-referenced actions harms them by delaying the creation of the biosurveillance network. But such a harm is speculative at best. Likewise, although Plaintiffs assert that “the lack of public input places Plaintiffs at risk of being subject to or harmed by uninformed, let alone unlawful, government action,” (Pls. Mem. at 15), there is no sufficient showing suggesting that Defendants are taking uninformed action. This risk of harm is therefore also

speculative.

C. ORGANIZATIONAL INJURY

"An organization is injured when there is a 'perceptible impairment of [the] organization's activities' due to the challenged conduct . . . but the injury must be far more than simply a setback to the organization's abstract social interests." Pen Am. Ctr. v. Trump, 448 F. Supp. 3d 309, 325 (S.D.N.Y. 2020) (internal quotation marks and citations omitted). This impairment may come in the form of forcing an organization to divert its resources. Id.

Plaintiffs' final argument as to irreparable harm based on diversion of organizational resources also fails. Plaintiffs explain that CIP has had to take certain actions as a result of Defendants' conduct, including devising reopening plans and reallocating resources to support remote learning and alternative in-person learning experiences, providing laptops, and giving financial counseling to families affected by COVID-19. Plaintiffs note that Housing Works has also had to divert resources to a series of COVID-19-specific programs and interventions, which it must continue so long as the pandemic remains uncontrolled. While the Court understands that Plaintiffs

have had to newly undertake these steps, Plaintiffs' diversion of resources is not due to Defendants' conduct -- rather, it is due to the pandemic. And while Plaintiffs seem to imply that fewer resources would have been devoted to pandemic-responsive programming had Defendants abided by their obligations, that argument is specious. The Court is not persuaded that the pandemic would have necessarily ended, or that its severity would have lessened, absent Defendants' alleged violations.

The Court is mindful of the toll the COVID-19 pandemic has taken on countless communities, including those that Plaintiffs serve. However, Plaintiffs have failed to show that they have suffered irreparable harm caused by Defendants' action or inaction as claimed in this case. Without such an actual and imminent showing that Plaintiffs' response to the pandemic has been substantially impaired, and would be improved by means of the disclosure of the information Defendants allegedly withheld, or by the enablement of the public participation opportunities at issue, or the other remedies Plaintiffs' Motion seeks, their request for injunctive relief must be denied.

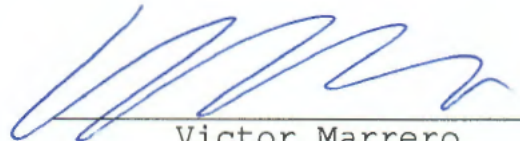
**IV. ORDER**

Accordingly, it is hereby

**ORDERED** that the motion of plaintiffs Coney Island Prep, Leslie-Bernard Joseph, Housing Works, Inc., Charles King, New York City Councilmember Mark Levine, and Alexandra Greenberg for a preliminary injunction (Dkt. No. 6) is **DENIED**.

**SO ORDERED.**

Dated: New York, New York  
11 December 2020

  
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Victor Marrero  
U.S.D.J.